MAY 1 3 2013

LSH (mangofilcon A) Soft (hydrophilic) Contact Lens

510(k) Summary

1. Applicant Information

Lagado Corporation
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Date Prepared: May 1, 2013

2. Device Information

Classification name: Soft hydrophilic contact lens
Device classification: Class II
Regulation number: 21 CFR 886.5925
Product code: LPL
Proprietary name:

LSH (mangofilcon A) Sphere Soft (hydrophilic) Contact Lens

LSH (mangofilcon A) Multifocal Soft (hydrophilic) Contact Lens

LSH (mangofilcon A) Toric Soft (hydrophilic) Contact Lens

LSH (mangofilcon A) Toric-Multifocal Soft (hydrophilic) Contact Lens

3. Predicate Devices

Lagado Corporation claims substantial equivalence to Benz- 3GX (hioxifilcon B) Soft (hydrophilic) Contact Lens as cleared for marketing in the United States in K964528 on March 10, 1997.

4. Description of Device

The LSH (mangofilcon A) is available as a spherical, multifocal, toric, and toric-multifocal lens. All LSH lenses are plasma treated in the dry state prior to initial hydration.

The lens material, (mangofilcon A), is a non-ionic hydrophilic copolymer that consists of 51% mangofilcon A (N,N-dimethyl acrylamide (NNDMA) polymer with 3-methacryloxy propyltris(trimethylsilyl)siloxane (TRIS)), trifluoroethyl methacrylate (TFEM), 2- hydroxyethyl methacrylate (HEMA), N-vinyl-2-pyrrolidone (NVP), cross-linked with ethyleneglycol dimethacrylate (EGDMA), and 49% water by weight.

Mangofilcon A is available in clear (no tint) with or without a UV absorber to block a significant amount of the UV radiation occurring between 200 and 400 nm (UVA and UVB). The UV absorber is 2-(5-chloro-2H-benzotriazole-2-yl)-6-(1,1-dimethylethyl)-4- ethenyl phenol (UVAM).

Mangofilcon A is available in Blue or Aqua visibility tints to assist with handling, and both colors are available with or without UV absorber. The Blue lenses are tinted using 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (21 CFR 73.3106), and the Aqua lenses are tinted using Phthalocyanine Green (21 CFR 73.312).

The LSH (mangofilcon A) Sphere, Multifocal, Toric, and Toric-Multifocal Soft (hydrophilic) Lenses for Daily Wear are hemispheric flexible shells of the following dimensions.

LSH (mangofilcon A)				
	Sphere	Multifocal	Toric	Toric-Multifocal
Diameter(s)	10.0 mm to 16.0 mm	14.0 mm to 16.0 mm		
Center Thickness (Low Minus Lens)	0.07 mm dry			
Center Thickness (Plus Lens)	Up to 0.50 mm			
Base Curve(s)	6.5 mm - 9.7 mm			
Powers	-20.00 D to +12.00 D	-20.00 D to +12.00 D	-20.00 D to +12.00 D	
Cylinder Powers	Not Applicable (N/A)		-0.50 D to 2.50 D in steps of 0.25 D	
Axes	Not Applicable (N/A)		0° to 180°	
Add Powers	N/A	+1.00 D to +3.25 D in steps of 0.25 D	N/A	+1.00 D to +3.25 D in steps of 0.25 D

The physical/optical properties of the lenses are:

Property	LSH Latheable Silicone Hydrogel
Oxygen Permeability (Dk) (35°C, Fatt Units)	49
Refractive Index	Dry - 1.470 Hydrated – 1.413
Specific Gravity	Dry – 1.112 Hydrated – 1.109
Linear Expansion Ratio	1.26
Water Content	49%
Visible Light Transmittance	96%T
Plasma Treatment Required	Yes
Shore D Hardness (in blank form)	≥83

5. Indications for Use

The LSH (mangofilcon A) Sphere Soft (hydrophilic) Contact Lens is indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity in a power range of +12.00 to -20.00 Diopters.

The LSH (mangofilcon A) Multifocal Soft (hydrophilic) Contact Lens is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity in a power range of +12.00 to -20.00 Diopters and have near add requirements up to 3.25 Diopters.

The LSH (mangofilcon A) Toric Soft (hydrophilic) Contact Lens is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or non-aphakic persons with non diseased eyes in a spherical power range of +12.00 to -20.00 Diopters and a cylinder power range of -0.50 to 2.50 Diopters.

The LSH (mangofilcon A) Toric-Multifocal Soft (hydrophilic) Contact Lens is indicated for the correction of presbyopia in myopic, hyperopic and astigmatic aphakic or non-aphakic patients with non-diseased eyes in a spherical power range of +12.00 to -20.00 Diopters, a cylinder power range of -0.50 to 2.50 Diopters and an add requirement up to 3.25 Diopters.

The lenses may be disinfected using chemical (not heat) disinfecting systems.

6. Performance Data

Non Clinical Data

In support of the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens a series of non clinical testing was conducted. Tests included physical/chemical analysis, shelf life stability testing and toxicology (cytotoxicity, systemic injection and ocular irritation).

Clinical Data

A three month clinical study was conducted to establish the safety and efficacy of the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens for daily wear. Seventy-five (75) patients were enrolled in the study (56 test/19 control). The data from the clinical trial demonstrates that the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens is safe and effective for its intended use. The risks and benefits of the subject device for patients are the same as for other silicone hydrogel contact lenses.

Conclusion

Based upon the test data presented, the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens is as safe, as effective and performs as well as the predicate device. A comparison of the new device and the predicate device is presented in Table 1.

7. Substantial Equivalence

Lagado Corporation claims that the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate device, Benz- 3GX (hioxifilcon B) Soft (hydrophilic) Contact Lens (K964528).

Based upon clinical and non clinical product testing presented in this application, the LSH (mangofilcon A) Soft (hydrophilic) Contact Lens for daily wear is as safe and effective as the predicate device when used for the requested indications and in accordance with the directions for use.

Table 1 Comparison to Predicate Device:

LSH (mangofilcon A) Soft (hydrophilic) Contact Lens Comparison Table		
PROPERTY	LSH Latheable Silicone Hydrogel (mangofilcon A)	Predicate Device BENZ 3GX (hioxifilcon B)
OXYGEN PERMEABILITY (Dk) (35°C, Fatt Units)	49	15
REFRACTIVE INDEX	Dry - 1.470	Dry - 1.507
	Hydrated – 1.413	Hydrated – 1.425
SPECIFIC GRAVITY	Dry – 1.112	Dry - 1.308
	Hydrated – 1.109	Hydrated – 1.136
LINEAR EXPANSION RATIO	1.26	1.3
WATER CONTENT	49%	49%
TENSILE STRENGTH	3.07 M Pa	$25g/mm^2$
% ELONGATION AT BREAK	470	186
VISIBLE LIGHT TRANSMITTANCE	96 % T	95 % T
PLASMA TREATMENT REQUIRED	Yes	No
Shore D HARDNESS (in Blank form)	≥ 83	≥ 90

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Lagado Corporation
% Ms. Ellen M. Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite 180
Wilmington, MA 01887

Re: K120756
Trade/Device Name: LSH (mangofilcon A) Sphere Soft (hydrophilic) Contact Lens
LSH (mangofilcon A) Toric Soft (hydrophilic) Contact Lens
LSH (mangofilcon A) Multifocal Soft (hydrophilic) Contact Lens
LSH (mangofilcon A) Toric-Multifocal Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft hydrophilic contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 1, 2013
Received: May 3, 2013

Dear Ms. Beucler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director,
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Lagado Corporation

Indications for Use

510(k) Number: K120756

Device Name: LSH (mangofilcon A) Soft (hydrophilic) Contact Lens

Indications for Use:

The LSH (mangofilcon A) Sphere Soft (hydrophilic) Contact Lens is indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity in a power range of +12.00 to -20.00 Diopters.

The LSH (mangofilcon A) Multifocal Soft (hydrophilic) Contact Lens is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity in a power range of +12.00 to -20.00 Diopters and have near add requirements up to 3.25 Diopters.

The LSH (mangofilcon A) Toric Soft (hydrophilic) Contact Lens is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or non-aphakic persons with non-diseased eyes in a spherical power range of +12.00 to -20.00 Diopters and a cylinder power range of -0.50 to 2.50 Diopters.

The LSH (mangofilcon A) Toric-Multifocal Soft (hydrophilic) Contact Lens is indicated for the correction of presbyopia in myopic, hyperopic and astigmatic aphakic or non-aphakic patients with non-diseased eyes in a spherical power range of +12.00 to -20.00 Diopters, a cylinder power range of -0.50 to 2.50 Diopters and an add requirement up to 3.25 Diopters.

The lenses may be disinfected using chemical (not heat) disinfecting systems.

Prescription Use____XX____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Livshitz -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:____K120756____